

Pennsylvania Department of Health

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION (POC)		(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:  <b>390111</b>	(X2) MULTIPLE CONSTRUCTION:  A. BLDG: <u>00</u> B. WING: _____		(X3) DATE SURVEY COMPLETED:  <b>05/22/2023</b>
NAME OF PROVIDER OR SUPPLIER: <b>HOSP OF THE UNI OF PA REPRODUCTIVE SURGICAL FACILITY, THE</b>		STREET ADDRESS, CITY, STATE, ZIP CODE: <b>3701 MARKET STREET PHILADELPHIA, PA 19104</b>			
STATE LICENSE NUMBER: <b>17461501</b>					
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S 0000	INITIAL COMMENT	S 0000			
	This report is the result of a State licensure survey conducted on August 3, 2022, and completed on October 31, 2022, at the Hospital Of the University Of Pennsylvania Reproductive Surgical Facility. It was determined the facility was not in compliance with the requirements of the Pennsylvania Department of Health's Rules and Regulations for Ambulatory Care Facilities, Annex A, Title 28, Part IV, Subparts A and F, Chapters 551-573, November 1999.				
S 0043		S 0043			
LABORATORY DIRECTOR'S OR PROVIDER/SUPPLIER REPRESENTATIVE'S SIGNATURE			TITLE:		(X6) DATE:

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S 0043	Continued from page 1  51.31 Exceptions - Principle  51.31. Principle  The Department may grant exceptions to this part when the policy and objectives contained therein are otherwise met, or when compliance would create an unreasonable hardship and an exception would not impair or endanger the health, safety or welfare of a patient or resident. No exceptions or departures from this part will be granted if compliance with the requirement is provided for by statute.  This REGULATION is not met as evidenced by:	S 0043	Tag 0043 – 51.31 Exceptions – Principle The Hospital of the University of Pennsylvania Reproductive Surgical Facility (HUP RSF) took prompt steps to report an event that was deemed an infrastructure failure by the Department of Health's Surveyor once it was identified as such on October 28, 2022. HUP RSF leadership, in coordination with Penn Medicine Risk Management, HUP Director of Patient Safety, and Office of General Counsel, determined that this event met the exception criteria for reporting as an infrastructure failure as a transfer of a PS-3 level patient to a higher level of care. The Infrastructure Failure was reported through the Pennsylvania Patient Safety Reporting System (PA-PSRS) on October 31, 2022.  The HUP RSF is taking the following measures to prevent reoccurrence: The HUP RSF Patient Safety Officer (PSO), the HUP RSF Administrator, and the HUP RSF Director of	Completion Date: <b>07/31/2023</b> Status: <b>APPROVED</b> Date: <b>06/20/2023</b>	

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S 0043	Continued from page 2	S 0043	<p>Nursing (DON) will review all safety events, with special attention to PS-3 level patients, for the HUP RSF and determine the severity and classification of the event. On October 26, 2022, the HUP RSF PSO, the HUP RSF Administrator and the HUP RSF DON reviewed all exceptions that had been granted to the HUP RSF by the Department of Health Division of Acute and Ambulatory Care and created a rubric outlining the exceptions and corresponding reporting requirements. Based upon this they determined that the only exception requiring reporting to the Department of Health as an infrastructure failure came under 28 Pa Code § Section 551.3 as related to PS-3 level patients, dated September 23, 2015. Upon further investigation they determined that none of the remaining exceptions had any Department of Health reporting requirements.</p> <p>HUP RSF leadership communicated this reporting requirement to Penn</p>		

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S 0043	Continued from page 3	S 0043	<p>Medicine's Risk Management Director on October 26, 2022 since the Risk Management Department submits infrastructure failure reports on behalf of the HUP RSF.</p> <p>Effective January 23, 2023 a representative of Penn Medicine Risk Management and the HUP Director of Patient Safety began attending the HUP RSF Patient Safety Committee quarterly meetings in order to review and provide increased coordination on safety events that occur in the HUP RSF. Additionally, on February 2, 2023, the HUP RSF Administrator and the HUP RSF DON began attending and reporting into weekly HUP Safety calls to discuss emerging safety trends relevant to the HUP RSF.</p> <p>The HUP RSF Administrator will work collaboratively with Penn Medicine's Risk Management so that HUP RSF Infrastructure and Serious Events are reported in accordance with Act 13 of 2002, Medical Care Availability and Reduction of Error</p>		

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S 0043	Continued from page 4	S 0043	<p>(MCARE), PSA, and Department of Health requirements.</p> <p>The HUP RSF will monitor its performance by the following: The HUP RSF PSO or designee will monitor safety events (serious events, infrastructure failure, and others) reported through Penn Medicine's occurrence reporting system. Safety events will be presented quarterly to the HUP RSF Patient Safety Committee and the Quality Assurance and Performance Improvement (QAPI) Committee for discussion and recommendations for sustained compliance with exception reporting requirements as part of ongoing quality assurance and performance improvement activities, beginning at the next scheduled quarterly committee meeting, July 24, 2023. Audits of medical records of all PS-3 level patients will be reviewed by the HUP RSF Medical Director, the HUP RSF DON and the HUP RSF Administrator to verify that all PS-3 level patients who are transferred to a higher level of care are reported to</p>		

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S 0043	Continued from page 5	S 0043	<p>DOH as infrastructure failure events. Audits will be reported at the next scheduled quarterly HUP RSF Patient Safety Committee and the Quality Assurance and Performance Improvement (QAPI) Committee meetings, July 24, 2023.</p> <p>Title of Person Responsible The HUP RSF Medical Director and HUP RSF Administrator are responsible for the Plan of Correction.</p> <p>Completion Date: July 31, 2023</p>		

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S 0043	<p>Continued from page 6</p> <p>Based on review of facility documents, medical records (MR), and interview with staff (EMP), it was determined the facility failed to comply with the required criteria as stated in the exception granted by the Department related to Section § 551.3 of the 28 Pa. Code related to PS3 level patients for one of one medical record reviewed (MR1).</p> <p>Findings include:</p> <p>Review on August 3, 2022, of facility document "Exception Request Approval" letter dated September 23, 2015, revealed: "You specifically requested that the Hospital of the University of Pennsylvania Reproductive Surgical Facility, a Class B facility, be allowed to provide care to patients with a physical status (PS) of 3. Your request was granted with the following requirements.... The facility is required to report all transfers to a hospital as an infrastructure failure under the Pennsylvania-Patient Safety Reporting System (PA-PSRS), you will also include information in the report to the Department that this was a PS-3 patient transfer."</p>	S 0043			

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S 0043	<p>Continued from page 7</p> <p>A request was made on August 3, 2022, to EMP3 and EMP4 by the survey team for patient transfers from the facility to a tertiary hospital. EMP3 provided documentation that MR1, a PS-3 level patient was transferred to a tertiary hospital, post surgical procedure performed by the facility on April 14, 2022. A request was made by the survey team for the required notification to the "Department" for the transfer of MR1. None was provided.</p> <p>A review of MR1 completed on August 3, 2022, revealed MR1 was admitted to the facility on April 14, 2022, for a Ultrasound Guided Egg Retrieval (retrieval of eggs from ovarian follicles with the guidance of ultrasound by needle aspiration through the vaginal wall, the bladder wall or the abdominal wall) with a PS-3 level and a pain scale score of 10 (10 was documented in MR1 as the worst pain ever, location abdomen), Further review of MR1 revealed a progress note authored by EMP7 "Pt (patient) experiencing severe pain, arrived to OR (operating room) and was assisted in moving to OR</p>	S 0043			



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S 0043	Continued from page 8  bed." Further review revealed MR1 was transferred from the facility to a tertiary hospital post surgical procedure via emergency medical services (911).  An interview conducted on August 3, 2022, at approximately 1:30 PM with EMP3 and EMP4 confirmed MR1, PS-3 level patient was transferred post surgical procedure to a tertiary hospital via emergency medical services (911). EMP3 and EMP4 confirmed the transfer of MR1 was not reported to the "Department" as required by the Exception Request Approval letter dated September 23, 2015, for a Class B facility. "Further interview confirmed the event was not reported to the "Department" within 24 hours of confirmation.  Cross reference: Regulation: 553.3(1), Tag (033A): Governing Body Responsibilities	S 0043			
S 033A		S 033A			

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S 033A	Continued from page 9  553.3 (1) Governing Body Responsibilities  553.3 Governing Body responsibilities include:  (1) Conforming to all applicable Federal, State, and local laws.  This REGULATION is not met as evidenced by:	S 033A	Tag 033A – 553.3 (I) Governing Body Responsibilities: Conforming to all applicable Federal, State, and local laws.  The Hospital of the University of Pennsylvania Reproductive Surgical Facility (HUP RSF) took prompt steps to ensure compliance with Act 13 of 2002, Medical Care Availability and Reduction of Error (MCARE), which states that "a medical facility shall report the occurrence of a serious event to the department within 24 hours of the medical facility's confirmation of the occurrence or discovery of the serious event." "A medical facility shall report the occurrence of an infrastructure failure to the Department within 24-hours of the medical facility's confirmation of the occurrence or discovery of the infrastructure failure." This requirement is based on the HUP RSF exception granted September 23, 2015, allowing the care of PS-3 level patient in a Class B facility.	Completion Date: <b>07/31/2023</b> Status: <b>APPROVED</b> Date: <b>06/20/2023</b>	

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S 033A	Continued from page 10	S 033A	<p>The HUP RSF is taking the following measures to ensure compliance requirements to report the occurrence of a serious event and infrastructure failure to the Department of Health and Patient Safety Authority within 24-hours of the medical facility's confirmation of the occurrence of the serious event and/or infrastructure failure:</p> <p>Reeducation of the HUP RSF medical staff and employees to the HUP RSF Patient Safety Plan: The HUP RSF medical staff will be informed of this regulation at the faculty meeting scheduled for May 31, 2023 by HUP RSF Medical Director, and will be reflected in the meeting minutes along with medical staff attendance. The HUP RSF nursing staff will be informed of this regulation at the next HUP RSF staff meeting scheduled for June 8, 2023, facilitated by the DON and will be reflected in meeting minutes along with nursing staff attendance.</p> <p>This plan of correction will be</p>		

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S 033A	Continued from page 11	S 033A	<p>presented to the HUP Trustee Board through its Executive Committee scheduled for June 12, 2023 for approval and any additional direction to HUP RSF leadership so that HUP RSF is in compliance with requirements to report the occurrence of a serious event and/or infrastructure failure to the Department of Health and Patient Safety Authority within 24-hours of the facility's confirmation of the occurrence of the serious event and/or infrastructure failure.</p> <p>Utilizing the direction given by the HUP Trustee Board through its Executive Committee, the Risk Management staff and the HUP RSF Patient Safety Officer or designee will monitor safety events (serious event, infrastructure failure, and others) reported through Penn Medicine's occurrence reporting system so that they may be reported within 24 hours of confirmation of a serious event or infrastructure failure. The safety events will be presented for discussion and</p>		

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S 033A	Continued from page 12	S 033A	<p>recommendations to the HUP RSF Patient Safety Committee and the Quality Assurance and Performance Improvement (QAPI) Committee at the next quarterly meeting scheduled for July 24, 2023 for sustained compliance with serious event and infrastructure event reporting as part of ongoing quality assurance and performance improvement activities. Audits of medical records of all PS-3 level patients will be reviewed by the HUP RSF Medical Director, the HUP RSF DON and the HUP RSF Administrator to verify that all PS-3 level patients who are transferred to a higher level of care are reported to DOH as infrastructure failure events. Audits will be reported at the next scheduled quarterly HUP RSF Patient Safety Committee and the Quality Assurance and Performance Improvement (QAPI) Committee meetings, July 24, 2023.</p> <p>Meeting minutes that contain the analysis of audits from the HUP RSF Patient Safety Committee and the Quality Assurance and Performance</p>		

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S 033A	Continued from page 13	S 033A	<p>Improvement (QAPI) Committee meetings will be reported up to the HUP Trustee Board ASF Coordinating Committee at the next scheduled meeting, July 31, 2023.</p> <p>The HUP RSF Medical Director and HUP RSF Administrator are responsible for the Plan of Correction.</p> <p>Completion date: July 31, 2023</p>		

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S 033A	Continued from page 14  Based on review of facility policy, documents, medical records (MR) and interview with staff (EMP), it was determined the facility was not in compliance with the Pennsylvania State Law (MCARE)-Act 13.  The Hospital Of The University Of Pennsylvania Reproductive Surgical Facility was not in compliance with Act 13 of 2002 Medical Care Availability and Reduction of Error (MCARE) Act 13 of 2002. Section 313. Medical facility reports and notifications. (a) Serious event reports.--A medical facility shall report the occurrence of a serious event to the department and the authority within 24 hours of the medical facility's confirmation of the occurrence of the serious event. The report to the department and the authority shall be in the form and manner prescribed by the authority in consultation with the department and shall not include the name of any patient or any other identifiable individual information. (b)..."- A medical facility shall report the occurrence of an infrastructure failure to the department within 24	S 033A			

Pennsylvania Department of Health

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NAME OF PROVIDER OR SUPPLIER: <b>HOSP OF THE UNI OF PA REPRODUCTIVE SURGICAL FACILITY, THE</b>  STATE LICENSE NUMBER: <b>17461501</b>		STREET ADDRESS, CITY, STATE, ZIP CODE: <b>3701 MARKET STREET PHILADELPHIA, PA 19104</b>			
(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE	(X5) COMPLETE DATE	
S 033A	<p>Continued from page 15</p> <p>hours of the medical facility's confirmation of the occurrence or discovery of the infrastructure failure. The report to the department shall be in the form and manner prescribed by the department."</p> <p>This is not met as evidenced by:</p> <p>Based on a review of facility policy, document, medical records (MR), and interview with staff (EMP), it was determined the facility was not in compliance with State Law based the requirement for reporting of a patient transfer event to a higher level of care for a PS-3 Level Patient in a Class B facility, according to an Exception Request Approval received from the "Department", for one of one medical record reviewed (MR1)</p> <p>Findings include:</p> <p>Review of facility policy "Hospital of the University of Pennsylvania Reproductive Surgical Facility (RSF) Patient Safety Plan" last reviewed June 2022 revealed II. Definition of Terms: Infrastructure Failure-An undesirable or unintended event,</p>	S 033A			



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S 033A	Continued from page 16  occurrence, or situation involving the infrastructure of the medical facility or the discontinuation or significant disruption of service, which could seriously compromise patient safety. ...IV. Components of Patient Safety Plan: D. Notification of Regulatory, Licensing and Accrediting Agencies. A serious event or incident will be reported to regulatory, licensing and/or accrediting agencies, if appropriate, within the applicable time period after consultation with the Office of the General Counsel. These agencies may include, but not be limited to, the Pennsylvania Department of Health, the Pennsylvania Patient Safety Authority, and the Joint Commission on the Accreditation of Healthcare Organizations...V. As noted in Section IV (D) above, an incident or occurrence will be reported to the appropriate external agencies within the applicable time frames after consultation with the Office of the General Counsel....E. Medical Staff and Employees-Members of HUP RSF's medical staff and the HUP RSF's employees are responsible for participating in and complying with the patient safety plan, including the timely reporting of serious	S 033A			

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S 033A	Continued from page 17  events and incidents"  Review on August 3, 2022, of facility document "Exception Request Approval" letter dated September 23, 2015, revealed: "You specifically requested that the Hospital of the University of Pennsylvania Reproductive Surgical Facility, a Class B facility, be allowed to provide care to patients with a physical status (PS) of 3. Your request was granted with the following requirements.... The facility is required to report all transfers to a hospital as an infrastructure failure under the Pennsylvania- Patient Safety Reporting System (PA-PSRS), you will also include information in the report to the Department that this was a PS-3 patient transfer."  Review of MRI, admitted on April 14, 2022, for a Ultrasound Guided Egg Retrieval revealed MR1 was transferred post surgical procedure to a tertiary hospital for additional medical services as ordered by OTH1, a physician via emergency medical services (911). A request was made by the survey team for the required notification to the	S 033A			

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S 033A	Continued from page 18  "Department" for the transfer of MR1. None was provided.  An interview conducted on August 3, 2022, at 2:00 PM with EMP3 and EMP4 confirmed MR1, a PS-3 Level patient was discharged by transfer from the facility via emergency medical services (911) on April 14, 2022, post surgical procedure to a tertiary hospital to receive additional medical services. Further interview confirmed the event was not report to the Department within 24 hours of confirmation. EMP2 stated "We were advised through hospital communications that the event did not need to be reported to the "Department."  Cross Reference: Regulation: 51.31(Tag 0043)- Exception Principle	S 033A			



# Certified End Page

**HOSP OF THE UNI OF PA REPRODUCTIVE SURGICAL FACILITY, THE**  
**STATE LICENSE NUMBER: 17461501**  
**SURVEY EXIT DATE: 05/22/2023**

**I Certify This Document to be a True and Correct Statement of Deficiencies and  
Approved Facility Plan of Correction for the Above-Identified Facility Survey**

A handwritten signature in black ink that reads "Jeane Parisi".

*Jeane Parisi*  
*Deputy Secretary for Quality Assurance*

A handwritten signature in black ink that reads "Debra L. Bogen MD".

*Debra L. Bogen, MD, FAAP*  
*Acting Secretary of Health*



THIS IS A CERTIFICATION PAGE

**PLEASE DO NOT DETACH**

THIS PAGE IS NOW PART OF THIS SURVEY